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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/125,888	08/27/1998	AGNETA PETTERSSON	1103326-0519	8291

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EXAMINER	
CHORBAJI, MONZER R	
ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 03/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/125,888	PETTERSSON ET AL.
	Examiner	Art Unit
	MONZER R CHORBAJI	1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 August 1998* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This final office action is in response to the communication received on 11/26/2003

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones (U.S.P.N. 3,442,686) in view of Gordon et al (U.S.P.N. 3,967,728) and further in view of Lambert (U.S.P.N. 4,585,666).

With respect to claim 1; Jones discloses a method (examples 1-16) of using a laminate as a barrier material against gases (col.2, lines 4-7), the method includes a container, which is formed of a laminate (col.5, lines 45-63) having an inner polypropylene layer (col.4, line 20 and col.8, lines 63-64), an outer polyethylene terephthalate layer (col.4, lines 60-62, col.8, lines 20-21, and col.8, lines 65-66), and an intermediate silicon oxide layer (col.1, lines 17-19). In addition, Jones's laminate acts as a barrier when exposed to gases in general (col.1, lines 25-27 and col.2, lines 5-12). However, Jones fails to explicitly teach the specific type of gas such as ethylene oxide and also fails to teach the following: a package, which contains a medical instrument having a hydrophilic outer surface coating, a sealed container which contains a sterile wetting fluid for wetting the hydrophilic coating of the instrument, the laminate is substantially impermeable to ethylene oxide gas, and exposing the package to ethylene oxide gas. Gordon et al, which is in the art of packaging catheters discloses the following: a package (11), which contains a medical instrument (12), a sealed container (17) which contains a sterile wetting fluid for wetting the instrument, the laminate of the container is substantially impermeable to ethylene oxide gas (17 and col.3, lines 45-48), and exposing the package to ethylene oxide gas (11 and col.3, lines 36-44). Gordon et al fails to disclose a medical instrument having a hydrophobic outer surface coating. Lambert teaches a method for coating a medical instrument such that the outer surface

is hydrophilic (see example 1). Thus, it would have been obvious to one having ordinary skill in the art to modify Jones method to include a medical instrument having a hydrophilic outer surface coating, which has a low coefficient of friction when wetted with a water based liquid (Lambert, col.1, lines 7-11).

With respect to claims 2-4, Jones teaches the following: the polyolefin is polypropylene (col.4, line 20); the polyester for the outer layer of the laminate is polyethylene terephthalate (col.4, lines 60-62 and col.8, lines 20-21); the polyamide is nylon (col.4, line 26).

With respect to claim 5, Gordon et al discloses a urethral catheter for bladder drainage (12).

With respect to claims 6-10; Jones discloses an intermediate layer, which includes a layer of silicon and a polymeric matrix (col.2, lines 30-36, lines 55-59, col.4, lines 13-18, and col.6, lines 31-34). Furthermore, since all the various types of polymers in claims 7-9 have been shown to be disclosed as indicated above, the choice of such types in the construction of the matrix is well within the scope of a person having an ordinary skill in the art of designing laminates.

Response to Arguments

5. Applicant's arguments filed 11/26/2003 have been fully considered but they are not persuasive.

On page 3 of the response, applicant argues, "Therefore, based on the examiner's own admission, Gordon et al best allegedly either discloses or suggests features 1, 4, and 5 which the examiner stated are missing from the primary reference

to Jones. Thus, after the combination of Jones and Gordon, items 2 and 3 are still missing". The examiner's comment on the Gordon et al reference is based on the scope of the attorney's arguments and not the complete disclosure of the reference. The Gordon et al reference still teaches the features mentioned on page 3 of the non-final office action dated may 19,2003.

On page 3 of the response, applicant argues, "There is no suggestion of either feature 2 or 3, i.e., a package containing a medical instrument having a hydrophilic outer surface coating or a sealed container containing a sterile wetting fluid for wetting the hydrophilic coating of the instrument". Features 2 and 3 are disclosed in the Gordon et al reference and in the Lambert reference as mentioned on pages 3-4 of the non-final office action dated may 19,2003. With regard to the hydrophilic outer surface coating feature, Lambert in example 1 discloses such a limitation.

On page 3 of the response, applicant argues, "Once again, the examiner has expressly stated that the Gordon reference is cited solely for its disclosure of the use of ethylene oxide as a sterilization gas. If, however, the examiner also relies on Gordon for a suggestion of features 2 and 3, then the claimed invention is distinguishable over the claimed invention because the claimed invention does not use a lubricant-containing pouch formed from a gas impermeable material such as a metal or aluminum foil as disclosed and required by Gordon". The examiner's comment on the Gordon et al reference is based on the scope of the attorney's arguments and is directed to medical packaging of catheters. The Gordon et al reference still teaches the features mentioned on page 3 of the non-final office action dated may 19,2003. With regards to

the structure of the laminate, the features of such a structure are disclosed in the Jones reference and not in the Gordon et al reference.

On page 4 of the response, applicant argues, "In the absence of impermissible hindsight, applicant submit that the ordinary practitioner would not be motivated to combine Jones, Gordon, and Lambert to arrive at a solution as represented by the claimed invention". Both Jones and Gordon et al references recognize that the laminate must be impermeable to gases (Jones, col.2, lines 7-78) and specifically to ethylene oxide gas as taught in Gordon et al, in col.3, lines 45-48. Lambert is combined for disclosing that a medical instrument having a hydrophilic outer surface coating is known. As a result, it would have been obvious to one having ordinary skill in the art to modify Jones method to include a medical instrument having a hydrophilic outer surface coating, which has a low coefficient of friction when wetted with a water based liquid (Lambert, col.1, lines 7-11).

On page 4 of the response, applicant argues, "Accordingly, applicant submit that the ordinary practitioner would not use Jones as a starting point for a method of using the prior art laminate in medical applications as a barrier material against ethylene oxide gas". The Jones reference recognizes that the laminate must be impermeable to all gases (Jones, col.2, lines 7-78) in general, meaning that ethylene oxide gas is included. Also, the Gordon et al reference recognizes that the laminate must be impermeable specifically to ethylene oxide gas (col.3, lines 45-48). Thus, the ordinary practitioner would use Jones as a starting point and combines with the Gordon et al reference for

the ethylene oxide gas impermeability, since Jones discloses the same building components of the laminate as the current claims do.

On page 5 of the response, applicant argues, "There is no suggestion by Gordon that a barrier material other than aluminum foil or a metal could be used to protect the lubricant from ethylene oxide". The Jones reference recognizes that the laminate must be impermeable to all gases (Jones, col.2, lines 7-78) in general, meaning that ethylene oxide gas is included. In addition, both the instantaneous claims and the Jones reference teach the same components of the laminate such that it is credible to believe that the laminate of Jones is capable of acting as barrier against ethylene oxide gas. The Gordon et al reference is used to show that it is recognized in the art to design barrier laminate specifically against ethylene oxide gas regardless of the components that make up such a laminate.

On page 5 of the response, applicant argues, "However, Lambert does not disclose or suggest that a hydrophilic coating is stable under sterilizing conditions, and in particular in the presence of ethylene oxide gas. Lambert does not give any guidance on the stability of the hydrophilic coating under such conditions". The Lambert reference is used only to show that medical instruments having a hydrophilic coating is known and not for considerations regarding the stability of the coating in the presence of ethylene oxide gas. Such considerations are a matter of routine experimentation when one skilled in the art would follow the teachings of the Jones and Gordon et al references.

On page 6 of the response, applicant argues, "Accordingly, one of ordinary skill would not be motivated to use this hydrophilic coating, which apparently does not require sterilization, with ethylene oxide sterilization as disclosed by Gordon. As such, there is no motivation to combine Lambert with either Jones or Gordon". The Lambert reference is only used to show that medical instruments having a hydrophilic outer surface coating are known and not for any method of sterilization. However, both the Jones and the Gordon et al references teach sterilizing medical instruments such that it would have been obvious to one having ordinary skill in the art to modify Jones method to include a medical instrument having a hydrophilic outer surface coating, which has a low coefficient of friction when wetted with a water based liquid (Lambert, col.1, lines 7-11).

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

7. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 8:30-5:00.

9. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (571) 272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Monzer R. Chorbaji
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